



## LACHRYMAL PLUGS AND METHODS FOR SETTING SAME

[0001] The present invention relates to lachrymal plugs and methods for positioning these devices.

[0002] It generally concerns means adapted to control the flow of tears running from the surface of the eye towards the nasal cavity.

[0003] The normal functioning of the human eye requires that its outer surface be constantly covered with a lubricating film constituted by tears, that ensure both rinsing and protection due to the natural anti-infectious antibiotics that they contain. They are produced by a series of glands located in the eyelids and about the periphery of the eye.

[0004] The deficiency in maintaining the stability of this film on the eyeball can cause various nuisances, such as stinging, irritations, burning sensations and sight deterioration in the case of dryness on the eye surface.

[0005] Tears are produced continuously, the excess of fluid being drained from the eyeball surface 1 through two point openings constituting the upper 2 and lower 3 lachrymal points located near the inner corner of the eye and communicating with ducts known as canaliculi 4, 5, that lead to a lachrymal sac 6 that opens out into the nasal cavity 7. The lachrymal points 2, 3 are capable of opening or closing in the manner of a sphincter-type muscle, so as to ensure controlling the flow of the fluid (Figure 1).

[0006] The lack of lachrymal fluid on the eyeball is generally due to a deficiency of the productive glands, which can be caused by age or by other factors.

[0007] It is possible to improve the situation by acting on the lachrymal ducts by completely or partially blocking them.

[0008] In particular, permanent blockage, possibly by surgery (cauterization, laser) of the lachrymal ducts, can be a method for treating tear-related deficiencies. When the flow of tears in the nasolachrymal sac is thus prevented, the volume of remaining tears generates greater moisture.

[0009] This method has the drawback of being irreversible, barring a new surgical intervention. To overcome this, removable devices capable of being positioned in a lachrymal duct and removed without surgical intervention have been proposed. For instance, the U.S. Patent No. 334,137, filed by the company "EAGLE VISION," describes a device for controlling the lachrymal fluid that blocks the flow of this fluid originating from the surface of the eye, and comprising an inverted truncated cone-shaped end portion and a head provided with a widened dome. The end portion is arranged to facilitate the positioning of the device through a point opening, and the widened dome prevents the complete penetration of the device into the vertical portion of the canaliculus through the point opening.

[0010] Nevertheless, this type of device has risks of accidental migration or expulsion. Furthermore, it requires a special apparatus for positioning and extraction, and it does not allow increasing the flow of the lachrymal fluid.

[0011] The Patent No. WO 98/33461, filed by Mr. Alain Fouéré, co-Applicant of the present application, describes a screwable meatus plug adapted to be implanted in the lachrymal points, and constituted of a substantially cylindrical body whose lateral surface comprises a helical threading, similar to that of a screw allowing to position it or remove it by screwing or unscrewing, the meatus plug comprising, or not, an axial through duct allowing the passage of a predetermined flow of lachrymal fluid.

[0012] However, this implant allows intervening only on the lachrymal points 2, 3, and not on the other parts of the tear flow system, such as the canaliculi 4, 5 (see Figure 1).

[0013] Given their design, the dimensions of known systems must be adapted to the morphology of each patient, which requires a more or less wide range of prostheses of each type, resulting in an increase of the manufacturing and storing costs.

[0014] The object of the device according to the present invention, which is essentially adapted to allow the blockage of the lachrymal ducts, is to overcome these circumstances in order to allow fighting against the disease,

often called "dry eyes," by overcoming a deficiency of the lachrymal glands through the decrease or suppression of the flow of tears towards the nasal cavities.

[0015] This device, which is particularly easy to implant, has the advantage of being easily adapted to various morphologies of the lachrymal ducts, which allows using one size for all patients.

[0016] It is constituted of a lachrymal plug adapted to be inserted in the lachrymal canaliculi; this plug, possibly provided with an axial duct, comprises on its outer walls flexible elements that can be folded on said walls to allow for the insertion of the plug in the lachrymal duct, and are capable of being straightened once the lachrymal plug is set so as to maintain the latter in position.

[0017] On the attached drawings, given by way of non-limiting examples of embodiments according to the present application:

- Figure 1, already cited, schematically shows an eye with the lachrymal ducts and the lachrymal sac,
- Figures 2 and 3 show a lachrymal plug according to the invention seen from the side and end, respectively,
- Figure 4 shows an alternative of the lachrymal plug of Figures 2 and 3 provided with pins having an increasing length,
- Figure 5 is an axial cross-sectional view showing the positioning of a lachrymal plug by means of a tube having a push rod,
- Figure 6 shows, in the same conditions, the lachrymal plug once in position,
- Figure 7 shows an alternative of the lachrymal plug of Figure 6, provided with pins having an increasing length,
- Figure 8 shows a lachrymal plug according to Figure 6 implanted in the lachrymal ducts, and
- Figures 9 and 10 are axial cross-sectional views of two examples of possible forms of the device that is the object of the invention.

[0018] The device, Figures 2-10, is constituted of a substantially cylindrical body 10, on the outer lateral walls of which are implanted flexible elements constituted of radial pins 11 that can be applied against these walls and straightened when they are released.

[0019] These flexible elements are predetermined to have sufficient elasticity to partially penetrate into the inner wall 12 of the canaliculus 4, 5, by straightening up, so as to ensure that the lachrymal plug is firmly held in position (Figure 5).

[0020] The pins 11 can be arranged in helical formation or any other configuration. Their length can be constant, increasing (Figures 4 and 7), decreasing or variable. They are advantageously tilted in the direction of the nasal cavities 7, so that they cannot be displaced by the natural peristalsis of the lachrymal duct which drives tears and foreign bodies inwardly.

[0021] The exact conformation of the body 10 can vary. For instance, it can have the form of a cone (Figure 9), a double cone (Figure 10), or even a diabolo.

[0022] The body 10 is possibly provided with an axial duct 13 allowing a reduced passage of the tears (Figure 10).

[0023] The device described can advantageously comprise at least one element, such as a flexible disk, arranged to ensure its impermeability.

[0024] The lachrymal plug can be made of any material allowing the pins 11, or other flexible elements, to be folded and straightened, whether it is metal or a synthetic material. In particular, it can be manufactured of shape memory metal, offering the possibility of installing it without an instrument.

[0025] It can possibly comprise a radio-opaque reference, visible with X-rays, to facilitate the marking during the progression of the lachrymal plug when it is positioned.

[0026] This positioning will be carried out by any known appropriate means allowing to press the pins 11 against the outer wall of the body 10, and to release them once the prosthesis is positioned.

[0027] In particular, this means can consist of a tube 15 having a push rod 16 (Figure 5), or of an instrument provided with jaws, similar to those of a mechanical pencil. Such an instrument would further be completely adapted for undertaking the removal of the prosthesis.

[0028] The positioning of the various constitutive elements gives the object of the invention a maximum of useful effects that, until now, had not been obtained by similar devices.